



Food and Drug Administration
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Siemens Medical Solutions USA, Inc.
% Elaine Medio, RAC
PET and PCS Regulatory Projects Manager
810 Innovation Drive
KNOXVILLE TN 37932

August 3, 2015

Re: K151486
Trade/Device Name: Biograph mCT and mCT Flow PET/CT Scanners
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: June 1, 2015
Received: June 2, 2015

Dear Ms. Medio:

This letter corrects our substantially equivalent letter of July 17, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Michael D. O'Hara For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151486

Device Name

Biograph mCT and mCT Flow PET/CT Scanners

Indications for Use (Describe)

The Siemens Biograph mCT systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.

The CT component produces cross-sectional images of the body by computer reconstruction of X-Ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The PET subsystem images and measures the distribution of PET radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and utilizes the CT for fast attenuation correction maps for PET studies and precise anatomical reference for the fused PET and CT images.

The system maintains independent functionality of the CT and PET devices, allowing for single modality CT and / or PET diagnostic imaging.

These systems are intended to be utilized by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors, disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning and interventional radiology procedures.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

Submitter: M. Alaine Medio, RAC
PET and PCS Regulatory Projects Manager
Siemens Medical Solutions USA, Inc.
Molecular Imaging
810 Innovation Drive
Knoxville, TN 37932

Manufacturers: Siemens Medical Solutions USA, Inc.
Molecular Imaging
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Knoxville, TN 37932

Siemens Medical Solutions USA, Inc.
Molecular Imaging
2501 North Barrington Road
Hoffman Estates, IL 60192

Telephone Number: (865)218-2703

Fax Number: (865)218-3019

Date of Submission: May 29th, 2015

Identification of the product

Device Proprietary Name: Biograph mCT and mCT Flow PET/CT Scanners

Common Name: Positron Emission Tomography (PET) System
Computed Tomography (CT) System

Classification Name: Emission Computed Tomography System per 21 CFR
892.1200
Computed Tomography X-Ray System per 21 CFR
892.1750

Product Code: 90 KPS and 90 JAK

Classification Panel: Radiology

Device Class: Class II

Marketed Devices to which Equivalence is claimed

Predicate:

Device Proprietary Name: Biograph mCT and mCT Flow PET/CT Scanners
Manufacturer: Siemens Medical Solutions USA, Inc.
Product Code: 90 KPS and 90 JAK
Device Class: Class II
510(k) Number: K123737

Reference Devices:

Device Name: Somatom Definition AS/AS+
Somatom Definition Edge
510(k) Numbers: K143400 (Somatom Definition AS/AS+)
K143401 (Somatom Definition Edge)

Device Description:

The Biograph mCT and mCT Flow PET/CT Scanners are combined multi-slice X-Ray Computed Tomography and Positron Emission Tomography scanners. These systems are designed for whole body oncology, neurology and cardiology examinations. The Biograph mCT systems provide registration and fusion of high-resolution metabolic and anatomic information from the two major components of each system (PET and CT). Additional components of the system include a patient handling system and acquisition and processing workstations with associated software.

Biograph mCT software is a command based program used for patient management, data management, scan control, image reconstruction and image archival and evaluation. All images conform to DICOM imaging format requirements.

The software for the Biograph mCT systems which is the subject of this application is substantially equivalent to the commercially available Biograph mCT software. Modifications include:

- Syngo software upgrade
 - Update of the syngo software to the latest revision (drivers, etc...)
- Somaris Software (cleared in K143400, K143401)
 - Upgrade to the latest revision of Somaris Software
 - Addition of new software features
 - Scan Time, Respiratory Rate and Pitch adjustments to provide for Full 4D lung scans

- Twin beam scanning feature for Biograph mCT-X and Biograph mCT Edge
- HD Field of View Pro
- Iterative Metal Artifact Reduction (iMAR)
- Temporal minimum intensity projection and temporal maximum intensity projections (tMIP)
- FAST 3D align / 3D Reconstruction
- FAST DE Results
- Respiratory Online mode
- Enhancements to the Iterative Reconstruction software (ADMIRE)
- PETsyngo software
 - Update of the software to add stitched whole body and stitched HD-Chest feature
 - Update to add Multi-series CT for Attenuation Correction
 - Summed whole body dynamic
 - Update of the software corrections
 - Update of the TrueD software component
 - Address anomalies related to loading of PET images
 - Update to improve usability
 - Improvements to workflow
 - Improvements to performance (faster reconstruction speeds)

Intended Use:

The Siemens Biograph mCT systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.

The CT component produces cross-sectional images of the body by computer reconstruction of X-Ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The PET subsystem images and measures the distribution of PET radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and utilizes the CT for fast attenuation correction maps for PET studies and precise anatomical reference for the fused PET and CT images.

The system maintains independent functionality of the CT and PET devices, allowing for single modality CT and / or PET diagnostic imaging.

These systems are intended to be utilized by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors, disease and organ function for the evaluation of diseases and disorders such as, but not limited to,

cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning and interventional radiology procedures.

Performance Testing / Safety and Effectiveness:

Performance testing for the CT subsystem was included in the original premarket notification for the CT subsystems and there have been no changes affecting this testing.

PET Testing in accordance with NEMA NU2:2012 was conducted on two different configurations of the Biograph mCT systems, a 3 ring version and a 4 ring version.

| Performance Criteria (Standard) | Results | Acceptance |
|------------------------------------|---------|--|
| Transverse Resolution FWHM @ 1 cm | Pass | ≤ 7.3 mm |
| Transverse Resolution FWHM @ 10 cm | Pass | ≤ 7.5 mm |
| Axial Resolution FWHM @ 1 cm | Pass | ≤ 6.0 mm |
| Axial Resolution FWHM @ 10 cm | Pass | ≤ 6.6 mm |
| Sensitivity @ 435 keV LLD | Pass | ≥ 5.0 cps/kBq (3R) ≥ 9.4 cps/kBq (4R) |
| Count Rate peak NECR | Pass | ≥ 95 kcps @ 30 kBq/cc (3R) ≥ 165 kcps @ 28 kBq/cc (4R) |
| Count Rate peak trues | Pass | ≥ 350 kcps @ 46 kBq/cc (3R) ≥ 575 kcps @ 40 kBq/cc (4R) |
| Count Rate bias (mean) | Pass | $\leq \pm 5\%$ |
| Scatter Fraction | Pass | $\leq 37\%$ (3R) $\leq 40\%$ (4R) |

All Performance testing met the predetermined acceptance values.

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions, USA Inc. adheres to recognized and established industry standards such as IEC 60601-1 series and 21 CFR 1020.30 and 21 CFR 1020.33 to minimize electrical, mechanical and radiation hazards.

Verification and validation of Siemens systems is performed in accordance with documented procedures, design and code reviews, test plans and specifications. Traceability of the requirements specified in the requirement specifications and functional specifications is ensured during component integration, software validation and system testing.

Statement regarding Substantial Equivalence:

There have been no changes implemented in the modifications to the Biograph mCT that impact either the fundamental technology or the indications for use. The Biograph mCT with the modifications outlined in this Premarket Notification is substantially equivalent to the currently commercially available predicate device.